

APPENDIX B

ESTIMATING THE TESTING COSTS

B.I. Introduction

In support of the proposed HAPs test rule, EPA prepared an economic analysis of the testing requirements described in the proposed rule based on the costs of performing tests under test guidelines that were in effect in 1995.¹ Since that time, eleven new TSCA test guidelines were added to part 799 of title 40 of the Code of Federal Regulations.² These series 799 test guidelines were developed from the public draft versions of the OPPTS harmonized test guidelines 870 series³ and are cross-referenced in the amended HAPS proposal (upcoming Federal Register publication).

This appendix provides additional information describing how EPA estimated the costs of testing each of the 21 HAP chemicals using eleven TSCA 799 test guidelines.

This appendix contains the following sections: “Methods,” which describes the approach used to obtain the cost estimates and “TSCA 799 Test Guideline Costs” which contains tables listing the cost estimates for each type of test and each chemical. The estimated costs for toxicity tests required by the amended HAPs proposal are summarized in Tables B.1 and B.2, which present both test-specific and chemical-specific costs. Test cost data are provided as three estimates for each test: best, minimum and maximum.⁴ Detailed tables with cost adjustment data and test guideline information are provided as supplementary information at the end of this appendix in Tables B.3 and B.4.

B.II. Methods

The amended HAPs proposal requires testing of HAPs chemicals using health effects test guidelines for acute inhalation toxicity with histopathology, subchronic inhalation toxicity, prenatal inhalation toxicity, reproduction and fertility effects toxicity, carcinogenicity, four tests for genetic toxicity, neurotoxicity, and immunotoxicity. The TSCA 799 series of health effect guidelines is the most recent effort by EPA to reflect the state-of-the-art for toxicity testing.

Prior to the publication of the eleven TSCA 799 series guidelines, EPA used draft versions substantially similar to the final guidelines to estimate costs of performing toxicity testing using these guidelines. Multiple changes in test guidelines are incorporated in the transition from the earlier test guideline series (795, 798, and 870) to the current TSCA 799 series.

¹ *Section 4 Test Rule Support for 21 Hazardous Air Pollutants, non-CBI version*, EPA/OPPT/EETD/RIB with the support of Mathtech, Inc., April 4, 1995.

² 62 FR 43820, August 15, 1997.

³ 61 FR 31522, June 20, 1996.

⁴ All manipulations and calculations discussed in subsequent sections were made to each of the three estimates, although the discussion uses the general term "cost" for simplicity of presentation.

The development of the test cost estimates for the TSCA 799 Series guidelines has three basic steps:

Step 1: Identify the most similar guideline for which a cost estimate is available

Step 2: Compare the TSCA 799 guideline to the most similar guideline for which a cost estimate is available to determine if adjustments are necessary

Step 3: Adjust the available cost estimate to obtain a cost estimate for the TSCA 799 guideline

B.II.1. Basic Cost Data

The principal elements of the total laboratory cost estimate⁵ for each toxicity test are total direct labor, overhead, other direct costs, general and administrative (G&A) costs and fee (as described below). Direct Labor. To determine total direct laboratory labor, the test guidelines are reviewed and summarized in an outline of the study protocol. The usual time required to complete each task in the protocol is estimated and the job category required for the task is determined. Total labor hours for each job category are multiplied by the hourly rate for the category to determine total labor costs. Salary rates are based on estimates of industry averages obtained from multiple sources.

Overhead. The overhead rate is applied as a percentage of total direct labor to cover the costs incurred by a laboratory in facility operation, fringe benefits, and indirect labor. Data from government contract bids and other sources were used in estimating this cost element.

Other Direct Costs. These include laboratory and related supplies, subcontracted services, and overtime costs. Standard costs for items were used along with costs for specialized services that require outsourcing (e.g., ophthalmological examinations required intermittently), and overtime required due to the 7 day-per-week, 24 hour-per-day operation of a laboratory.

General and Administrative (G&A) Services. Costs for salaries to cover activities such as accounting, personnel, purchasing, payroll, legal services, and marketing are included in this cost element. These are less variable than overhead costs and average 15 percent in most businesses.

Fee. Fees vary markedly. The variability is determined by such factors as capacity, capabilities, test duration, test type, and current market conditions.

Cost Range. The cost range is calculated by substituting the lowest and highest expected overhead rates into the total cost calculation. Overhead is used as the main variable because it is the most significant cost component in the overall test cost and can vary greatly from company to company and within specific departments within a company.

Best Estimate. The best estimate is based on professional judgement and is usually the midpoint of the cost estimate range.

⁵ Cost estimates for past test guidelines were developed by EPA under contract No. 68-W6-0022. Detailed information on guideline cost estimates is available in "TSCA Test Guidelines: Cost Estimates for Health Effects Testing" (OPPT/EETD/RIB various dates) which is available in the public record for this rulemaking.

B.II.2. Adjustments

Types of Adjustments

To obtain cost estimates for the toxicity tests required by the amended HAPs proposal, various adjustments were made to modify the available cost information. This was necessary because cost estimates were not always available for the species or route of exposure of interest. Adjustments were also necessary to account for inflation, in cases where the test estimates were made prior to 1996. A description of general adjustments that were made to the available cost estimates is given below. This is followed by a description of the specific adjustments required to calculate the costs for each type of test.

Inflation Adjustments

For all data more than one year old, cost estimates were adjusted for inflation through 3/31/97 using the GDP Implicit Price Deflator.

Scaling Adjustments

Many test costs were "scaled" using a multiplier derived from available cost estimates to determine estimated costs for the species and routes of exposure required in the amended HAPs proposal. This was done by reviewing the available estimates for species and routes of exposure to determine the ratio of costs between tests with the species and exposure routes of interest. This ratio was used as a multiplier to derive estimated costs for those not available. For example, cost estimates were not available for the four-hour neurotoxicity assays in rats via the inhalation route, as specified in the amended HAPs proposal. However, cost estimates were available for the four-hour neurotoxicity assay in rats exposed via gavage test. Cost estimates on both gavage and inhalation were available for chronic toxicity, oncogenicity, and combined chronic and oncogenicity tests (guidelines 870.4100, 870.4200, and 870.4300). The ratios of the inhalation/gavage costs for these three guidelines are 1.19, 1.27, and 1.52, respectively, and the average ratio is 1.33. This average ratio was considered reasonably representative of the inhalation/gavage cost ratio. To obtain the final four-hour neurotoxicity cost estimate for exposure via inhalation, the ratio (1.33) was multiplied by the cost estimate for a gavage study ($1.33 \times \text{gavage cost} = \text{inhalation test estimate}$).

In cases where scaling was carried out, tests were selected as the source of ratios because they matched as closely as possible to the type, duration, exposure, and the nature of the required test. A specific example of this is the scaling of the *in vivo* bone marrow test costs that was carried out using the similar *in vivo* erythrocyte test cost estimate. Although there are small differences in test protocols and duration, the application of scaling factors in this manner is a relatively accurate approach to cost estimation.

Averaging Adjustments

In cases where a general test description was provided in the amended HAPs proposal, and only specific cost estimates were available, the average cost of the specific tests was calculated and used as representative of the general test type. For example, when an inhalation exposure route was specified and only costs for the specific inhalation phases (e.g., vapor and aerosol) were available, the average cost for the two phases was calculated to obtain an average value for the inhalation test. The average is listed as the cost estimate. When multiple species were required or allowed (e.g., with regard to the developmental toxicity and carcinogenicity tests) an average cost for the two or three species having cost data was also provided.

Test-specific Cost Modifications

The following section describes the procedure used to estimate costs for performing each of the eleven TSCA 799 test guidelines, identifies the substantive differences between available cost estimates and required test guidelines, and identifies adjustment factors applied. This discussion, including the exact source of available cost estimates, is summarized in Table B.3.

See Table B.1 for the estimated costs of each of the tests required in the amended HAPs proposal and Table B.2 for the chemical-specific costs of tests required in the amended HAPs proposal.

Acute Inhalation Toxicity Test and Acute Test Modification (799.9135)

Test cost estimates were available for the acute toxicity test via the correct route of exposure and in an acceptable species. Consequently, scaling was not necessary. The cost estimates were adjusted for inflation as described above. For this test, an inhalation exposure route was specified and only costs for the specific inhalation phases (e.g., vapor and aerosol) were available. The average cost for the two phases were calculated to obtain a representative value for the test. The average is listed in row three of Table B.3 for the cost estimates (best, best adjusted, etc.)

Neurotoxicity Screen (799.9620)

The neurotoxicity screening cost estimates for both the 4-hour and 90-day tests were made in 1997 and therefore did not need to be adjusted for inflation. However, cost estimates for the 4-hour test were available only for gavage exposure, and 90-day test cost estimates were available only for dietary exposure. Both required scaling to obtain a cost estimate for the inhalation route of exposure specified in the regulations.

4-hour test

The 4-hour test cost estimates were multiplied by a derived scaling factor (1.33) to obtain the estimated costs for inhalation exposure. The value of 1.33 was obtained from a review of the relationships between the costs of the gavage and inhalation exposure routes for three tests for which cost data were available for both routes of exposure: chronic toxicity, oncogenicity, and combined chronic and oncogenicity (guidelines 870.4100, 870.4200, and 870.4300). The ratios of the costs (inhalation costs/gavage costs) for these three tests is 1.19, 1.27, and 1.52, respectively, and the average cost ratio is 1.33.

Example using the "best cost estimate":

The best estimate of the cost of the 4-hour test via gavage is \$77,040. This value was multiplied by 1.33 to obtain the cost adjusted for the inhalation route of \$102,463. This is listed in Table B.3 as the “best” adjusted cost.

90-day test

There were no relevant cost estimates available for the 90-day test regarding the ratio between dietary exposure and inhalation exposure tests. Consequently, a two-step process was required to obtain a cost estimate for the 90-day neurotoxicity test for the inhalation route, because only dietary data were available. The dietary to gavage ratios were calculated first, followed by application of the gavage to inhalation ratio discussed in the paragraph above. Guidelines 870.6300, 870.7800, and 870.3100 with cost ratios of 1.006, 1.036, and 1.07 were used as the basis for the dietary to gavage ratio, yielding an average ratio of 1.037. The test cost estimate for the dietary 90-day neurotoxicity assay was multiplied by this value to obtain an estimate of the cost for a gavage test. Then the multiplier for the gavage to inhalation ratio (1.33, described in the paragraph above) was multiplied by the value obtained in the estimated gavage cost (the cost obtained in the first step), to obtain the final inhalation cost estimate.

Example using the "best cost estimate":

The 90-day dietary test cost of \$112,110 was multiplied to 1.037 and then by 1.33 to obtain a cost estimate for the 90-day test via the inhalation route of \$168,512, which is listed as the best adjusted cost estimate in Table B.3.

Combined test cost assumption

The neurotoxicity test requirement specifies that a short-term test be carried out, and, depending on the results obtained, a subchronic test may be required. It was assumed for the cost estimates that both tests would be carried out. This provides an estimate of the maximum (or worst case) costs that may be incurred for this test group.

Subchronic Test and Subchronic Test Modification (799.9346)

Test cost estimates for the subchronic toxicity test via the inhalation route were made in 1997. Consequently, there was no adjustment required for the basic test. However, there are no cost estimates available for the modifications required under these proposed regulations that specify respiratory system lavage and pathological evaluation. To obtain an estimate of the costs, a review of the testing requirements under this modification was made. The requirement to carry out lavage and pathological evaluation are in addition to numerous other types of pathological evaluations and tissue preparation specified in the standard subchronic test guideline. Taking this information into account, it was estimated that the additional requirements, beyond the basic test activities, would increase the cost of the test by approximately 20 percent. The total costs listed for this test reflect the sum of the basic test plus the test modification.

Developmental Toxicity Test (799.9370)

Estimating the cost of the developmental toxicity test requirement is complex because multiple species are required for many chemicals and the cost data available for each species varies. An average cost was calculated for the developmental toxicity test because the testing of two species of mammals are required for some chemicals. Both mouse and rat cost estimates are available via the correct route of exposure

(inhalation) and were used in the cost estimate. However, mouse or rat tests are excluded in the proposed rule for some chemicals; consequently, a third species was needed. Rabbit cost estimates were available and used in this analysis. To obtain an average cost for multiple species, first adjustments for inflation were made to cost estimates for each of the three species to standardize the basis for averaging. Because both rat and mouse cost estimates required inflation adjustments (they were from 1994 and 1995), all three of the species cost estimates were adjusted through the first quarter of 1997, even though the rabbit cost estimates are less than one year old. This was done in order to provide a consistent basis for averaging the three estimates. In all cases the cost estimates were modified for inflation as described above.

The second step was to obtain estimates for each of the three species exposed via the inhalation route. Inhalation exposure cost data were available for both the mouse and rat, so scaling was not required. However, cost estimates for mice were available for only specific phases of inhalation exposure: vapor and aerosol. Consequently, the average of these two estimates were calculated to obtain an average estimate for the inhalation exposure test cost for mice.

Estimates for rabbit inhalation test costs were not available, and scaling was required from test cost estimate for the gavage route of exposure. No cost estimates were available for rabbits exposed by both the gavage and inhalation exposure routes, so a ratio could not be calculated directly from rabbit test cost estimates. The scaling factor obtained from the ratio of test costs for rats exposed via gavage and inhalation was used to scale the test cost estimates for rabbits. It is reasonable to assume that the ratios for these two mammalian species are similar (1.33). The derivation of this ratio is described above in the neurotoxicity screen discussion above.

To obtain an average test cost for conducting tests in two species, the costs for the three species were summed and multiplied by 2/3 (multiplied by 1/3 to obtain an average value and multiplied by 2 to obtain costs for 2 species).

Example using the “best cost estimate”:

The sum of the inflated cost for the rat of \$86,560, the inflated and averaged cost for the mouse of \$87,800, and the scaled and inflated cost for the rabbit of \$161,729, was calculated and yielded a total cost estimate of \$336,089. Two thirds of this cost is \$224,060, which is the final “best” estimate of the cost for the test when two species are required to be tested.

Reproductive Test (799.9380)

The reproductive toxicity test costs were estimated within the last year, so no inflation adjustment was necessary. The test cost estimates were for exposure via gavage. Consequently a scaling factor of 1.33 (as described in the neurotoxicity screen discussion above) was applied to the gavage cost estimate to obtain a cost estimate for the inhalation route of exposure.

Carcinogenicity Test (799.9420)

The carcinogenicity toxicity test costs were estimated within the last year, so no inflation adjustment was necessary. The costs for carcinogenicity tests are based on either:

- 1) a requirement that a male rat and female mouse are used, or

2) no species requirement.

In the first case, a “blended” cost was calculated using the sum of ½ of the rat test cost and ½ of the mouse test cost (in effect the average of the two test costs). In the second case, use of the average cost for mice and rats (the two species for which cost estimates are available) was used to estimate the test costs. This value is the same as the blended value $(\text{[mouse+rat]}/2)$.

Immunotoxicity Test (799.9780)

The immunotoxicity test costs were estimated within the last year, so no inflation adjustment was necessary. The test cost estimates were available for rats exposed via gavage. As no species was specified in the proposed rule, the rat cost estimates were used as representative of the costs for this test. To obtain an inhalation cost estimate, a scaling factor of 1.33 was applied to the gavage cost estimates for the rats.

***In Vivo* Bone Marrow Test (799.9538)**

The *in vivo* bone marrow test costs were estimated within the last year, so no inflation adjustment was necessary. Test cost estimates were for rats exposed via gavage. As no species requirement was listed in the proposed rule, the rat data were used as representative of the costs of this test. Scaling was required, however, to obtain a cost estimate for inhalation exposure. Scaling data were obtained from a similar type of test: the *in vivo* erythrocyte test (870.5395). A comparison of the gavage and inhalation routes of exposure for this test yielded a ratio of 1.1. This ratio was multiplied by the gavage test cost data for the bone marrow test to obtain adjusted estimate of the test cost.

***In Vivo* Erythrocyte Test (799.9539)**

The *in vivo* erythrocyte test costs were estimated within the last year, so no inflation adjustment was necessary. Test cost estimates were available for two time periods: 1- and 3-day tests in rats. As no species requirement was listed in the proposed rule, the rat cost estimates were used as representative of the costs for this test. The average of these two test costs was calculated to obtain the estimated average cost.

Mutation Somatic Cell Culture (799.9530)

The mutation somatic cell culture test costs for the appropriate type of tests (C.O. and mouse) were estimated in 1994 and therefore required adjustment for inflation. The costs for the two types of tests are the same, and a single inflated set of cost estimates are reported.

***E. Coli* - Mutation Test (799.9510)**

The *E. coli* mutation test costs were estimated within the last year, so no inflation adjustment was necessary. The *E. coli* test requirement is a modification of an older test requirement that specified five cell mutation assays be carried out. The original guideline focused on salmonella testing; the new requirements specify that one of the five tests be carried out on *E. coli*. It is not anticipated that this change in bacterial species will alter the test costs significantly. Consequently, the test costs for salmonella were used to estimate the test costs for the revised guideline with the *E.coli* requirement. Both Azo and direct plate Salmonella testing costs were provided in earlier cost estimates and were very similar. The average of the costs for the two test types was used as the cost estimate for this test requirement.

B.III TSCA 799 Series Guideline Costs

This section contains summary tables of cost data organized by test and by chemical. Table B.1 summarizes the cost estimates for each type of test. Test costs were estimated as described in the preceding “Methods” section. (A table providing supplementary information to Table B.1, and containing summaries of the adjustments to the cost estimates is provided at the end of this section in Table B.3.)

TABLE B.1 - Estimated Laboratory Costs of Toxicology Tests Required in Amended HAPs Proposal

Test Description	TSCA 799 Series Guideline (40 CFR)	Laboratory Test Costs		
		Best	Min	Max
Acute Inhalation Toxicity with Acute Modification	799.9135 with (ASTM E 981-84)	70,029	56,940	84,149
Neurotoxicity Screen	799.9620	270,975	218,741	327,748
Subchronic with Subchronic Modification	799.9346	328,440	193,488	466,836
Developmental	799.9370	224,060	177,198	273,800
Reproductive	799.9380	566,221	426,092	765,601
Carcinogenicity	799.9420	763,930	611,020	994,590
Immunotoxicity	799.9780	73,137	52,801	96,412
In Vivo Bone Marrow	799.9538	38,302	31,460	45,705
In Vivo Erythrocyte	799.9539	13,915	11,150	16,855
Mutation Somatic Cell Culture	799.9530	16,066	12,766	19,641
E. Coli - Mutation	799.9510	5,905	4,420	7,460

Table B.2 contains laboratory test cost estimates for each chemical. It lists the costs for each type of test required under the amended HAPs proposal, using costs shown in Table B.1 and the total costs for each chemical. (A table providing supplementary information to Table B.2, and containing summaries of the cost adjustments is provided at the end of this section in Table B.4.)

Table B.2: Chemical-specific Laboratory Costs of Tests Required in Amended HAPs Proposal

CAS Number	HAP Chemical	Protocol Title	Cost		
			Best	Min.	Max.
79-00-5	1,1,2-Trichloroethane	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Developmental	224,060	177,198	273,800
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Carcinogenicity	763,930	611,020	994,590
		In Vivo Bone Marrow	38,302	31,460	45,705
		In Vivo Erythrocyte	13,915	11,150	16,855
		Immunotoxicity	73,137	52,801	96,412
		Total	2,349,008	1,778,890	3,071,696
120-82-1	1,2,4-Trichlorobenzene	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Developmental	224,060	177,198	273,800
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	638,200	505,680	782,109
92-52-4	1,1'-Biphenyl	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Developmental	224,060	177,198	273,800
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	1,532,861	1,125,260	2,014,546
463-58-1	Carbonyl Sulfide	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Developmental	224,060	177,198	273,800
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Carcinogenicity	763,930	611,020	994,590
		E. Coli Mutation	5,905	4,420	7,460
		Mutation-Somatic Cell Culture	16,066	12,766	19,641
		In Vivo Bone Marrow	38,302	31,460	45,705
		In Vivo Erythrocyte	13,915	11,150	16,855
		Immunotoxicity	73,137	52,801	96,412
		Total	2,370,979	1,796,076	3,098,797
7782-50-5	Chlorine	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Total	70,029	56,940	84,149
108-90-7	Chlorobenzene	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	742,581	521,970	975,145
126-99-8	Chloroprene	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	980,362	754,574	1,273,910
95-48-7	Cresol, ortho-isomer	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	742,581	521,970	975,145
106-44-5	Cresol, para-isomer	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	742,581	521,970	975,145

Table B.2: Chemical-specific Laboratory Costs of Tests Required in Amended HAPs Proposal

CAS Number	HAP Chemical	Protocol Title	Cost		
			Best	Min.	Max.
108-39-4	Cresol, meta-isomer	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	742,581	521,970	975,145
111-42-2	Diethanolamine	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Developmental	224,060	177,198	273,800
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	1,532,861	1,125,260	2,014,546
100-41-4	Ethylbenzene	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Developmental	224,060	177,198	273,800
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	1,204,421	931,772	1,547,710
107-06-2	Ethylene Dichloride	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Developmental	224,060	177,198	273,800
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Total	1,459,725	1,072,459	1,918,134
107-21-1	Ethylene Glycol	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	742,581	521,970	975,145
7647-01-0	Hydrochloric Acid	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Total	70,029	56,940	84,149
7664-39-3	Hydrogen Fluoride	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Developmental	224,060	177,198	273,800
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	1,532,861	1,125,260	2,014,546
108-31-6	Maleic Anhydride	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Developmental	224,060	177,198	273,800
		Neurotoxicity Screen	270,975	218,741	327,748
		Carcinogenicity	763,930	611,020	994,590
		Immunotoxicity	73,137	52,801	96,412
		Total	1,402,130	1,116,700	1,776,699
108-10-1	Methyl Isobutyl Ketone	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Reproductive	566,221	426,092	765,601
		Immunotoxicity	73,137	52,801	96,412
		Total	709,387	535,833	946,162
80-62-6	Methyl Methacrylate	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Developmental	224,060	177,198	273,800
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	1,204,421	931,772	1,547,710

Table B.2: Chemical-specific Laboratory Costs of Tests Required in Amended HAPs Proposal					
CAS Number	HAP Chemical	Protocol Title	Cost		
			Best	Min.	Max.
91-20-3	Naphthalene	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Reproductive	566,221	426,092	765,601
		Immunotoxicity	73,137	52,801	96,412
		Total	709,387	535,833	946,162
108-95-2	Phenol	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Immunotoxicity	73,137	52,801	96,412
		Total	143,166	109,741	180,561
85-44-9	Phthalic Anhydride	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Developmental	224,060	177,198	273,800
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Carcinogenicity	763,930	611,020	994,590
		Immunotoxicity	73,137	52,801	96,412
		Total	2,296,791	1,736,280	3,009,136
75-35-4	Vinylidene Chloride	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Neurotoxicity Screen	270,975	218,741	327,748
		Total	341,004	275,681	411,897

Supplementary Information

Two tables are contained in this section that provide additional detail regarding adjustments made to determine costs for specific toxicity tests (Table B.3) and testing costs for individual chemicals (Table B.4). Narrative text is provided to explain each column in the tables, due to their complexity. The “Methods” section of this appendix explains the adjustments listed in these tables in more detail.

Table B.3 Test-Specific Cost Estimate Modifications

Test cost information for the amended HAPs proposal are listed for each type or group of tests, with the specific species and route requirements listed in from the amended HAPs test rule. The adjustments made to the cost estimates are listed in the table footnotes and described in detail in the section above titled: “Test-specific Modifications.”

Column-by-column explanation of Table B.3

Test description: generic name of the test

Guidelines: Over the past several years, EPA has referred to similar test guidelines by different citation numbering systems. The guideline series citation numbers are listed in this column. The 795 or 798 series included in parts 795 or 798 of Title 40 of the Code of Federal Regulations were originally used by the Office of Toxic Substances. The 870 series guidelines refer to a “harmonized” system developed for by the Office of Prevention, Pesticides, and Toxic Substances. The part 799 series of Title 40 of the Code of Federal Regulations refers to a set of guidelines that was promulgated on August 15, 1997. While some test guidelines are identical to guidelines under previous numbering systems, others have been modified. Costs of performing tests under the eleven TSCA 799 series test guidelines to be used in the amended HAPs proposal were estimated primarily from the existing cost estimates for the 795, 798, and 870 series guidelines.

Cost Source: Existing cost estimate reports were used as the basis for all cost estimates. The test guideline that served as the basis for the cost estimate is shown first. The specific date of the estimates is shown in parentheses.

Species and Route Required and Available: The species and route required in the proposed HAPs test rule available in the cost source are shown. For example, “--/Rat” means that the species in the test rule is not specified and the species for which information was available was the rat. When these differ, it was necessary to scale the cost data to obtain appropriate cost estimates.

Other Factors: These include information that is used to define a test cost category, such as route, duration, species, etc.

Adjustment Type: Adjustments to original cost estimates were necessary for most tests due to inflation, the need to scale test data from available test cost data to the required test, or to obtain average cost values. The specific adjustments made to obtain each adjusted cost are listed in the footnotes of the table. They are also discussed for each test in the “Test-specific Modifications” section below.

Cost: The best, minimum, and maximum cost estimates are provided for each test as listed in the cost reports. Adjusted costs are listed in the adjacent columns. The range reflects variations in testing protocols

and cost differences among laboratories. The best estimate is based on professional judgement and is usually the midpoint of the range of costs.

Lab Hours: Labor hours required to perform the tests are listed. These were taken from the cost estimates listed in the “cost source” column. They are based on estimates of the laboratory time required to conduct the testing.

Totals

Total estimates within a test category are listed in the bottom row for each test. Totals were required when a test had multiple components (e.g., acute inhalation toxicity plus the modification for mouse sensitization). The adjusted totals are the final values, which have been modified, as required, by scaling, inflating, etc. In some cases, where adjustments were not required, there are no data listed in the adjustment columns. The final values are highlighted by gray boxes. These are the values used in Table B.4 to estimate the chemical-specific test costs.

Table B.3 here

Table B.4 Chemical-Specific Costs for Tests Required in Amended HAPs Proposal

Table B.4 contains chemical-specific cost data. Table B.3 is linked to Table B.4 through the use of its test categories and the final adjusted cost estimates. Chemicals are listed in order of CAS number with the required tests and additional requirements shown in the proposed test rule for each chemical. The codes used in the Special Requirement column are the same as those listed in the amended HAPs proposal and are explained in a key on the last page of the table. (The reader is referred to the amended HAPs test rule proposal for details on these specifications.) The total cost of all tests required for each chemical is shown in bold.

Put table B.4 here.